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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

09/466,568

12/17/1999

GERALD R. CRABTREE

APBI-P16-316

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28120

7590

06/03/2004

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EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/466,568 | Applicant(s) CRABTREE ET AL. | |
| | Examiner Terry A. McKelvey | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 18, 22, 23, 49-55, 57-61, 63-66, 68 and 69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 49, 54, 55, 57-61 and 63 is/are allowed.
- 6) ☒ Claim(s) 14, 18, 22, 23, 50-53, 64-66, 68 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All objections and rejections not repeated in the instant Action have been withdrawn due to applicant's response to the previous Action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/28/03 has been entered.

Specification

The disclosure is objected to because of the following informalities: the presence of handwritten note on page 57. See the attached copy of page 57; the handwritten note is in the right margin. The left margin notes are internal PTO notes,

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which are kept to the left margin and thus the right margin note does not appear to be a PTO note.

Appropriate correction is required.

Double Patenting

Claim 18 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62-129 of U.S. Patent No. 6,165,787 for reasons of record.

Claims 23, 50-53, 65, 66, 68, and 69 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-71 of U.S. Patent No. 6,043,082 for reasons of record.

Claims 18, 22, and 23 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 87-142 and 154-162 of U.S. Patent No. 5,869,337 for reasons of record.

Claims 14, 18, and 64 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 72-202 of U.S. Patent No. 5,834,266 for reasons of record.

Claims 14, 18, and 22 stand rejected under the judicially created doctrine of obviousness-type double patenting as being

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unpatentable over claims 14-28, 37, 38, 40, 43-52, and 60-62 of U.S. Patent No. 6,117,680 for reasons of record.

Response to Arguments

In the applicant's response filed 11/28/03, the applicant indicates that terminal disclaimers (for each of the double patenting rejections) will be submitted if necessary, upon indication of allowable subject matter. Because the TDs have not yet been submitted, the instant rejections remain of record until the proper TDs are submitted.

Conclusion

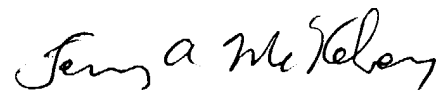
Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

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Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

June 1, 2004

Attachment

ARIAD 316-D

SUB

D11

COO⁺

excess of the *Xho*I-*Sal*I FKBP12-containing fragment from FK12/KS and ligated. After cloning, the plasmids comprising the desired constructs having the myristoylation sequence, CD3 and FKBP12 multimers in the 5'-3' direction were isolated and verified as having the correct structure. See Figs. 2 and 4.

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B. Construction of expression cassettes for intracellular signaling chimeras

The construct MZ/pBJ5 (MZE/pBJ5) is digested with restriction enzymes *Xho*I and *Sal*I, the TCR ζ fragment is removed and the resulting vector is ligated with a 10 fold excess of a monomer, dimer, trimer or higher order multimer of FKBP12 to make MF1E, MF2E, MF3E or MF_nE/pBJ5. Active domains designed to contain compatible flanking restriction sites (i.e. *Xho*I and *Sal*I) can then be cloned into the unique *Xho*I or *Sal*I restriction sites of MF_nE/pBJ5.

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15 Example 7. Construction of Nuclear Chimera

A. GAL4 DNA binding domain - FKBP domain(s) - epitope tag. The GAL4 DNA binding domain (amino acids 1-147) was amplified by PCR using a 5' primer (#37) that contains a *Sac*II site upstream of a Kozak sequence and a translational start site, and a 3' primer (#38) that contains a *Sal*I site. The PCR product was isolated, digested with *Sac*II and *Sal*I, and ligated into pBluescript II KS (+) at the *Sac*II and *Sal*I Sites, generating the construct pBS-GAL4. The construct was verified by sequencing. The *Sac*II/*Sal*I fragment from pBS-GAL4 was isolated and ligated into the IFK1/pBJ5 and IFK3/pBJ5 constructs (containing the myristoylation sequence, see Example 6) at the *Sac*II and *Xho*I sites, generating constructs GF1E, GF2E and GF3E.

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5' end of PCR amplified product:

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5' CGACACCGCGGCCACCATGAAGCTACTGTCTTCTATCG

SacII |----Gal4 (1-147)---->>
M K L L S S I

Kozak